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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,513	06/22/2006	John Brownlie	ERP02.003APC	3443

20995 7590 10/19/2009

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EXAMINER	
BLUMEL, BENJAMIN P	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
10/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/522,513	BROWNLIE ET AL.	
	Examiner	Art Unit	
	BENJAMIN P. BLUMEL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *128,129,131-136,144,164 and 165* is/are pending in the application.

4a) Of the above claim(s) *144* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *128, 129, 131-136, 164 and 165* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/27/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments.

Election/Restrictions

This application contains claim 144 is drawn to an invention nonelected without traverse in the reply filed on 9/2/08. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 128, 129, 131-136, 164 and 165 are examined on the merits.

Response to Arguments

Applicant's arguments with respect to claims 128, 129, 131-136, 164 and 165 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(New Rejection Necessitated by Amendments) Claims 128, 129, 131 and 135 are rejected under 35 U.S.C. 102(b) as being anticipated by Parker et al. (US Pat. 5,672,350).

The claimed invention is drawn to an immunogenic composition for raising an immune response against a coronavirus in a dog, the composition comprising: a coronavirus Spike protein having at least 90% amino acid identity with a CRCV S protein or an immunogenic fragment

thereof, or a nucleic acid encoding said coronavirus S protein or immunogenic fragment thereof: and a pharmaceutically acceptable adjuvant. The comparative S protein can be a BCV, HCV or CRCV S protein and should be at least 97% identical to that of at least 200 amino acids from SEQ ID NO: 4. MPEP § 2111.02 (II) recites, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction."

Parker et al. teach the generation of a recombinant, immunogenic composition based on bovine coronavirus E2 proteins (i.e., Spike proteins). The compositions also contain adjuvants for aiding in immune response elicitation. Furthermore, based on Appendix A, one of the spike (E2) protein employed by Parker et al. is 95.2% homologous with that of SEQ ID NO: 4 (S protein of CRCV strain T101) of the instant application. Appendix A also reveals that from residues 1101 to 1363 (262 amino acids), the S protein of Parker et al. possess a 97.7% identity with the corresponding region of SEQ ID NO: 4. Therefore, Parker et al. anticipate the claimed invention. *See columns 2, 9 and 10.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(New Rejection Necessitated by Amendments) Claims 128, 131, 134, 135, 164 and 165 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knape et al. (US Pat. 6,974,577 B2), Genbank Accession # AAF25499 (2000) and Hajer and Storz (Archives of Virology, 1979).

The claimed invention is drawn to an immunogenic composition for raising an immune response against a coronavirus in a dog, the composition comprising: a coronavirus having a Spike (S) protein with at least 90% amino acid identity with Canine Respiratory Coronavirus (CRCV) S protein and a pharmaceutically acceptable adjuvant. In addition, the comparative coronavirus S protein can be from BCV, HCV or CRCV and should be at least 97% identical to that of at least 200 amino acids from SEQ ID NO: 4. The coronavirus is either inactivated or attenuated. MPEP § 2111.02 (II) recites, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction."

Knape et al. teach the development of a bivalent bovine coronavirus/rotavirus immunogenic composition. The viruses employed can either be inactivated or attenuated and various adjuvants can also be used. Some examples of such adjuvants are IFA, alginate and aluminum hydroxide. However, they do not teach the use of a coronavirus with a S protein that is at least 97% identical to that of at least 200 amino acids from SEQ ID NO: 4.

Genbank accession # AAF25499 provides the S protein of bovine coronavirus LY-138. Based on Appendix B, the spike protein of LY-138 is 96% identical to SEQ ID NO: 4 (the spike

protein of CRCV strain T101) and Appendix C reveals a 98% identity when the same alignment is restricted to residues 1141 to 1363 of SEQ ID NO: 4.

Hajer and Storz teach the purification of BCV LY-138 and the subsequent analysis the structural proteins of the virus.

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Knape et al. in order to utilize the Bovine strain LY-138 in the production of an immunogenic composition. One would have been motivated to do so, given the suggestion by Knape et al. that the attenuated or inactivated bovine coronaviruses by used in the formation of an immunogenic composition. There would have been a reasonable expectation of success, given the knowledge that BCV LY-138 shares a high degree of homology with that of a CRCV S protein, as taught by Genbank Accession # AAF25499, and also given the knowledge that BCV LY-138 was publicly available prior to the instant invention, as taught by Hajer and Storz. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

(New Rejection Necessitated by Amendments) Claims 128, 131, 134-136, 164 and 165 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knape et al. (US Pat. 6,974,577 B2), Genbank Accession # AAF25499 (2000) and Hajer and Storz (Archives of Virology, 1979) Acree et al. (US Pat. 4,567,043).

The claimed invention further contains at least one of the following:

(a) an agent capable of raising an immune response in a dog against canine parainfluenza virus (CPIV);

(b) an agent capable of raising all immune response in a dog against canine adenovirus type 2 (CAV-2);

(c) an agent capable of raising an immune response in a dog against canine herpesvirus (CHV); and

(d) an agent capable of raising an immune response in a dog against Bordetella bronchiseptica

Acree et al. teach that compositions based on canine coronaviruses can also be combined with other canine agents, such as Canine Adenovirus 2, Canine Parainfluenza and Canine rotavirus. However, Acree et al. do not teach a coronavirus spike protein that is at least 90% identical to a CCV or at least 97% identical to a 200 amino acid fragment of SEQ ID NO: 4. *See column 6.*

The teachings of Knape et al., Genbank Accession # AAF25499 and Hajer and Storz are discussed above.

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Acree et al. in order to incorporate a bovine coronavirus that meets the identity requirements presently claimed. One would have been motivated to do so, given the suggestion by Acree et al. that multivalent compositions can be developed based on combining different agents with canine coronavirus. There would have been a reasonable expectation of success, given the knowledge that BCV LY-138 shares a high degree of homology with that of a CRCV S protein, as taught by Genbank Accession # AAF25499, also given the knowledge that BCV LY-138 was publicly available prior to the instant invention, as taught by Hajer and Storz, and also given the knowledge that coronaviruses with spike proteins the meet the identity requirements

was previously known, as taught by Knape et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646